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TRANSMITTAL FORM

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Total Number of Pages in This Submission: 9*

Application Number	11/692,338
Filing Date	10-23-2003
First Named Inventor	Terri L. Butler
Art Unit	1623
Examiner Name	Traviss L. McIntosh III
Attorney Docket Number	BP.028US2

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☑ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):

Remarks

Reference documents with explanation thereof.

* Not including references & post card

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name			
Signature	Kathleen R. Terry		
Printed name	Kathleen R. Terry		
Date	28 November 2005	Reg. No.	31,884

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	Kathleen R. Terry		
Typed or printed name	Kathleen R. Terry	Date	28 November 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Terri L. Butler et al.	Examiner:	Traviss C. McIntosh, III
Serial Number:	10/692,338	Group art unit:	1623
Filed:	23 October 2003	Docket:	BP.028US2
Title:	COMPOSITIONS AND METHODS FOR IMPROVING CARDIOVASCULAR FUNCTION		

SUPPLEMENTAL INFORMATION DISCLOSURE

Dear Examiner McIntosh:

Enclosed please find a Supplemental Information Disclosure listing the documents cited in the European search report for the EPO national phase, based on the above application. Copies of the non-US patent references are included. Here are my comments on these references:

1. USP 6,159,942: this patent, filed by the present applicant, discusses the use of ribose in healthy persons, not those undergoing cardiac rehabilitation. Example 5 shows a patient with coronary artery disease, who was considered to be healthy following coronary artery bypass grafting. He had no angina even on treadmill testing. Example 6 shows a person recovering from a severe bacterial infection. He is described as recovered, with no overt disease. It would not be known from this study whether cardiac patients requiring rehabilitation could benefit from low doses of oral ribose.

2. USP 6,218,366: this patent, filed by the present applicant, describes an acute study for the purpose of uncovering hibernating myocardium. Example 5, considered by the EPO Examiner to be relevant is a short term, three day, trial of ribose at high doses of about 13 grams per administration. Example 6 discusses potential benefits of co-administering a vasodilator with ribose but is silent on the dosage to be administered.

3. JA02286620: describes the use of a polysaccharide, including a ribose polysaccharide, found in green tea. No further description of this polysaccharide is provided.

4. MAHONEY: this paper reports that ribose cannot be used as a sole energy source in the isolated working rat heart. These findings say nothing about low doses of ribose supplemented with the energy sources of a normal diet in intact mammals.

5. ZIMMER: intact rats were subjected to regional cardiac ischemia. Recovery was found to be enhanced by very high levels (200 mg/kg/hour) of intravenously administered ribose. It should be pointed out that these were young, healthy animals subjected to an acute ischemic event, while cardiac patients have a chronic condition that develops over time and need chronic therapy. See also the discussion of Dr. Pliml's paper below.

6. LOSCALZO: this paper is a fine review of the state of knowledge of the ubiquitous cell effector nitric oxide in 1995. No mention is made of ATP resynthesis or an effect of ribose on nitric oxide generation.

7. CYR [sic: St. Cyr]: this paper is discussed in conjunction with the next reference, that of Dr. Pliml.

8. Pliml et al: Dr. Pliml has tried for many years, possibly based on the Dr. St. Cyr 1989 paper, to find a way to use ribose in various conditions. As discussed in the St. Cyr affidavit previously submitted to you (copy attached for your convenience) the original work by Drs. John Foker and John St. Cyr was one of the first attempts to study ribose in an intact mammal. In the study, healthy dogs weighing about 25 kilograms were subjected to twenty-minute cardiac cross-clamping. After this induced global ischemia, ATP levels were very low (about 50%) of preop levels) and ribose was given intravenously to enhance recovery. The dosage of ribose was about 17 grams per day with 100% bioavailability. Following the teachings of Dr. Foker and Dr. Zimmer, Dr. Pliml's study of 20 men with ischemic heart disease used correspondingly high doses of oral ribose, that is, 60 grams a day in four doses. A baseline treadmill exercise assessment was performed. After three days of ribose administration, , treadmill exercise

time to angina was improved. The dosage was not continued chronically to determine whether the effect would persist or even provide further improvement. It is our experience that doses over eight grams cause unacceptable gastrointestinal distress and therefore patient non-compliance would affect chronic use. In addition, it should be noted that Dr. Pliml co-administered glucose with the ribose. Dr. Pliml never discovered that the low doses of ribose without coadministered glucose as defined in the present claims could be effective and could be administered chronically.

I trust that these remarks will assist you in evaluating these newly presented references. Since there has not yet been an office action, I believe that no fee is due. If that is incorrect, please so notify me.

Respectfully submitted,

Kathleen R. Terry

Attorney for Applicants
Kathleen R. Terry
Reg. No. 31,884
(651) 659-9819
Krterry@visi.com

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
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First Named Inventor	Terri L. Butler
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Attorney Docket Number	BP.028US2

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 6,159,942	12 -10-2000	John A. St. Cyr, et al	Examples 1-7
		US- 6,218,366	4-17-2001	John A. St. Cyr et al	Examples 5,6
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
		JP 02 286620 A	11-26-1990	Riide Chem KK	Abstract	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

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Application Number	10/692,338
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First Named Inventor	Terri L. Butler
Art Unit	1623
Examiner Name	Traviss C. McIntosh III
Attorney Docket Number	BP.028US2

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		MAHONEY, J.R. ET AL.: "A comparison of Different Compounds..." J. of Surg. Res., Vol.47, 1989, pages 530-534, Acad. Press, San Diego, CA US	
		H.-G. ZIMMER ETAL. "Ribose accelerates..." J. of Mol. & Cel. Cardiol. Vol. 16, 1984, pages 863-866, Acad. Press, :London, UK	
		LOSCALZO ET AL. "Nitric oxide..." Progress in Cardiovas. Dis., Vol. 38, pages 87-104, 1995, Saunders, Philadelphia, PA US	
		CYR [sic] ET AL "Enahnced high energy...." J. of Surg. Res., Vol. 46 pages 157-162, 1989 Acad. Press, San Diego, CA, US	
		PLIML, W. ET AL. "Effects of Ribose...." The Lancet, Vol. 340, pages 507-510, Lancet Limited, London, UK 1992	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.